PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Fischetti, et al.

Continuation of Serial No.09/752,731 Group: 1616

Filed: 09/16/03 Examiner: Dameron Levest Jones

For: Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Various Illnesses

The Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Madam:

Please make the following amendments

IN THE TITLE

Please replace the title with the following:

A PARENTERAL COMPOSITION FOR TREATING BACTERIAL ILLNESSES

IN THE SPECIFICATION

Please amend Page 1, line 3 to read as follows:

This application is a continuation of U.S. Patent Application No. 09/752,731 filed January 3, 2001, is a continuation of in part of U.S. Patent Application No. 09/482,992, filed January 14, 2000, now US Patent No. 6,264,945 which is a continuation in part of U.S. Patent Application No. 09/395,636, filed September 14, 1999, now U.S. Patent No. 6,056,954.

IN THE CLAIMS

Please cancel claims 60-81.

Please add the following claims::

82) A parenteral therapeutic agent for the treatment of bacterial infections, said parenteral therapeutic agent produced by the method of:

(a) obtaining an effective amount of at least one enzyme genetically coded for by bacteriophage specific for a specific bacteria, wherein said at least one enzyme is selected from the group consisting of lytic enzymes, shuffled lytic enzymes, chimeric lytic enzymes, holin lytic enzymes, and combinations thereof, said at least one enzyme having the ability to digest a cell wall of a specific said bacteria; and,

(b) mixing (a) with a parenteral carrier for the parenteral delivery of said at least one lytic enzyme to the site of the infection.

83) The parenteral therapeutic agent according to claim 82, wherein the at least one said

enzyme is for the treatment of *Pseudomonas*.

84) The parenteral therapeutic agent according to claim 82, wherein the at least one said enzyme is for the treatment of *Streptococcus*

85) The parenteral therapeutic agent according to claim 82, wherein the at least one said enzyme is for the treatment of *Staphylococcus*.

86) The parenteral therapeutic agent according to claim 82, wherein said composition further comprises a buffer that maintains pH of the composition at a range between about 4.0 and about 9.0.

87) The parenteral therapeutic agent according to claim 86, wherein the buffer maintains the pH of the composition at the range between about 5.5 and about 7.5.

88) The parenteral therapeutic agent according to claim 86, wherein said buffer comprises a reducing reagent.

89) The parenteral therapeutic agent according to claim 88, wherein said reducing reagent is dithiothreitol.

90) The parenteral therapeutic agent according to claim 86, wherein said buffer comprises a metal chelating reagent.

91) The parenteral therapeutic agent according to claim 90, wherein said metal chelating reagent is ethylenediaminetetracetic disodium salt.

92) The parenteral therapeutic agent according to claim 86, wherein said buffer is a citrate-phosphate buffer.

93) The parenteral therapeutic agent according to claim 86, further comprising a bactericidal or bacteriostatic agent as a preservative.

94) The parenteral therapeutic agent according claim 82, further comprising administering a concentration of about 100 to about 500,000 active enzyme units per milliliter of fluid.

95) The parenteral therapeutic agent according to claim 82, further comprising administering the concentration of about 1000 to about 100,000 active enzyme units per milliliter of fluids.

96) The parenteral therapeutic agent according to claim 82, wherein said therapeutic agent

is administered intravenously.

97) The parenteral therapeutic agent according to claim 82, wherein said therapeutic agent is administered intramuscularly.

98) The parenteral therapeutic agent according to claim 82, wherein said therapeutic agent is administered subcutaneously.

99) The parenteral therapeutic agent according to claim 82, wherein the therapeutic agent further comprises at least one complementary agent which potentiates the bactericidal activity of the lysine enzyme, said complementary agent being selected from the group consisting of penicillin, synthetic penicillins bacitracin, methicillin, cephalosporin, polymyxin, cefaclor, Cefadroxil, cefamandole nafate, cefazolin, cefixime, cefmetazole, cefonioid, cefoperazone, ceforanide, cefotanme, cefotaxime, cefotetan, cefoxitin, cefpodoxime proxetil, ceftazidime, ceftizoxime, ceftriaxone, cefriaxone moxalactam, cefuroxime, cephalexin, cephalosporin C, cephalosporin C sodium salt, cephalothin, cephalothin sodium salt, cephapirin, cephradine, cefuroximeaxetil, dihydratecephalothin, moxalactam, loracarbef, mafate and chelating agents.

100) The parenteral therapeutic agent according to claim 82, wherein said at least one said

holin lytic enzyme is a shuffled holin lytic enzyme.

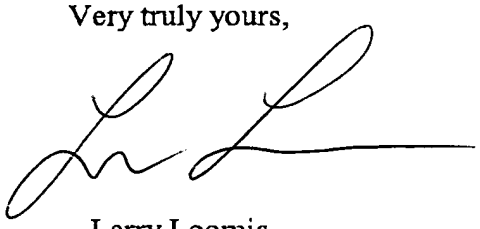
101) The parenteral therapeutic agent according to claim 82, wherein said at least one holin enzyme is a chimeric holin lytic enzyme.

102) The parenteral therapeutic agent according to claim 82, further comprising at least one lytic enzyme which is not selected from the group consisting of at least one shuffled lytic enzyme, chimeric lytic enzyme, and holin lytic enzyme.

REMARKS

The application is now in condition for allowance. Please call the undersigned at 800-888-5015 if you have any questions or comments. Thank you.

Very truly yours,



Larry Loomis